UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

INVERNESS MEDICAL SWITZERLAND GmbH and UNIPATH DIAGNOSTICS, INC., Plaintiffs,	)	
v.	)	CIVIL ACTION NO. 03-11323-PBS
ACON LABORATORIES, INC. Defendant.	)	

MEMORANDUM AND ORDER

July 16, 2004

Saris, U.S.D.J.

Plaintiffs Inverness Medical Switzerland GmbH and Unipath Diagnostics (collectively, "Inverness") seek a preliminary injunction barring Acon Laboratories, Inc. ("Acon") from making, using, selling or offering to sell various immunoassay test products, including pregnancy and ovulation test strips, and seek summary judgment that Acon's test devices infringe claims 5, 6, 7, 18, 19, and 22 of U.S. Patent No. 6,485,982 (Nov. 26, 2002) (the "'982 patent"). Acon has moved for summary judgment of invalidity of claims 5, 6, 7, 18, 19, and 22 of the '982 patent. Inverness relies primarily on claims 7 and 19 of the '982 patent, which involve a "one-step device," and has represented that both claim 7 and claim 19 cover all of Acon's products. The Court therefore restricts its discussion to these claims.

After hearing, Plaintiffs' motion for a preliminary

injunction is **ALLOWED** and Plaintiffs' motion for summary judgment is **ALLOWED** with respect to infringement of claims 7 and 19. Defendant's motion for summary judgment is **DENIED**.

FACTUAL BACKGROUND

The following facts are undisputed unless otherwise stated:

A. The '982 Patent

The '982 patent, entitled "Test Device and Method for Colored Particle Immunoassay," involves various immunoassay testing devices, like pregnancy and ovulation tests, which use colored particles to provide a visible signal of the testing results.[1]

Under the terms of the license agreement with patent owner Armkel LLC, Inverness Switzerland is the exclusive licensee of the '982 patent in the area of sales to professional users, such as doctors, hospitals, and professional health care facilities. (Bridgen Decl. ¶5.) It also has the right to sue for infringement of the '982 patent regardless of whether infringement occurs in the point of care field or the consumer field.[2]

In lay terms, the patent describes a test device for

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[1] An immunoassay is defined as a "test that measures antigen or antibody." Julias M. Cruse and Robert E. Lewis, Illustrated Dictionary of Immunology 311 (2d ed. 2003).

[2] The Court does not address Acon's standing arguments as the addition of Armkel LLC as a plaintiff renders those arguments moot.

detecting the presence of substances (or "ligands")[3] in liquids, the result being displayed as the accumulation of color (or lack thereof) on a test site that is connected with the site at which the liquid is applied through a flow path. In the embodiment at issue here, "sandwich-type" assays (so named because various elements combine together), the color appears because prior to the liquid reaching the test site, a "binder" joins the target ligand to a colored particle to form a "conjugate." This conjugate, when it reaches the test site by means of the flow path, joins with a "second binder," which has been immobilized at the test site. As a result, colored particles that are bound to the ligand accumulate at the test site, resulting, after sufficient accumulation, in the appearance of a color visible to the naked eye.

One common example of this mechanism is a type of pregnancy test. When a woman becomes pregnant, elevated levels of the hormone human chorionic gonadotropin ("hCG") arise in her urine. When a pregnant woman's urine is applied to this type of pregnancy test, the hCG binds with the first binder, forming a conjugate with a colored particle. The urine travels through the flow path to the test site, where the conjugate bonds with the immobilized second binder. When sufficient particles have become

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[3] A ligand is: "A molecule that binds or forms a complex with another molecule such as a cell-surface receptor." Dictionary of Immunology at 381.

bound, the accumulation of colored particles causes color to appear in the test site, indicating pregnancy.

Claim 5 provides:

> A test device comprising a conjugate and a test strip;
> the conjugate comprising a first binder for a ligand and a colored particle bound thereto, the conjugate forming a complex with the ligand when present together in liquid;
> the test strip comprising a sorbent material defining a flow path extending from a sample application site to at least a test site, the flow path guiding therealong transport of the conjugate and a liquid suspected to contain a ligand;
> a second binder for capturing the ligand or the complex, the second binder being immobilized at the test site;
> whereby accumulation of colored particles at the test site produces a color visible to the unaided eye indicative of the presence of the ligand in the liquid.

Claim 6 states: "The test device of claim 5 wherein the conjugate is disposed in the flow path upstream of the test site and is mobilizable along the flow path with passing liquid." Claim 7 states: "The test device of claim 6 wherein the conjugate is in dry form."

Claims 18 and 19 parallel claims 5 and 6-7, although they describe a method rather than a device. Claim 19 states: "The method of claim 18, wherein the conjugate is dried in the flow path upstream of the test site, the liquid sample is applied upstream of the dried conjugate, and the conjugate is mobilized along the flow path by passing liquid."

The specification describes both a two-step (or "pre-mix")

test, wherein the liquid is mixed with the conjugate before application to the test device (usually in a test tube), and a one-step (or "pee-on") test, wherein a person does not need to mix the liquid with the conjugate before application to the test device, but rather can add liquid directly to the test device, which performs the mixing automatically.

B. Acon

Defendant Acon sells various immunoassay products, including pregnancy tests, ovulation tests, infectious disease tests, and tests for use of illegal drugs. Acon's products are sold in the same markets as Inverness's products.

DISCUSSION

I. Applicable Standards

A. Preliminary Injunction Standard

The Court has the authority to grant preliminary injunctive relief in patent cases "in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283. However, this relief is a "drastic and extraordinary remedy that is not to be routinely granted." Intel Corp. v. ULSI Sys. Tech., Inc., 995 F.2d 1566, 1568 (Fed. Cir. 1993).

To obtain a preliminary injunction, the movant must show each of the following four factors: 1) a reasonable likelihood of success on the merits; 2) irreparable harm in the absence of a

preliminary injunction; 3) the balance of hardships weighs in favor of the movant; and 4) the public interest favors an injunction. Id.; see also Nutrition 21 v. United States, 930 F.2d 867, 869 (Fed. Cir. 1991). To obtain a preliminary injunction, a patent holder must show that there exists a reasonable likelihood of success on the merits with regard to the infringement of its patent by the defendant and the validity of its patent. Hybritech Inc. v. Abbott Labs., 849 F.2d 1446, 1451 (Fed. Cir. 1988).

B. Summary Judgment Standard

"Summary judgment is appropriate when 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.'" Barbour v. Dynamics Research Corp., 63 F.3d 32, 36 (1st Cir. 1995) (quoting Fed. R. Civ. P. 56(c)). "To succeed [in a motion for summary judgment], the moving party must show that there is an absence of evidence to support the nonmoving party's position." Rogers v. Fair, 902 F.2d 140, 143 (1st Cir. 1990); see also Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986).

"Once the moving party has properly supported its motion for summary judgment, the burden shifts to the non-moving party, who 'may not rest on mere allegations or denials of his pleading, but must set forth specific facts showing there is a genuine issue

for trial.'" Barbour, 63 F.3d at 37 (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986)). "There must be 'sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable or is not significantly probative, summary judgment may be granted.'" Rogers, 902 F.2d at 143 (quoting Anderson, 477 U.S. at 249-50) (citations and footnote in Anderson omitted). The Court must "view the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor." Barbour, 63 F.3d at 36.

II. Analysis

A. Infringement

"Determining whether a patent has been infringed involves two steps: (1) claim construction to determine the scope of the claims, followed by (2) determination whether the properly construed claim encompasses the accused structure." Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998). An accused device may infringe a given patent claim, and thus the patent, in one of two ways: literally, or under the doctrine of equivalents. Jurgens v. McKasy, 927 F.2d 1552, 1560 (Fed. Cir. 1991). "Literal infringement requires that the accused device contain each limitation of the claim [at issue] exactly; any deviation from the claim precludes a finding of literal infringement." Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d

1449, 1454 (Fed Cir. 1998).

To construe a patent claim, courts principally consult evidence intrinsic to the patent, including the claims themselves, the specification, and the prosecution history. Deering Precision Instruments v. Vector Distribution Sys., Inc., 347 F.3d 1314, 1322 (Fed. Cir. 2003). The Court indulges a strong presumption that claim terms carry their ordinary and customary meaning. Id. The ordinary meaning of a claim must be determined "from the standpoint of a person of ordinary skill in the relevant art." Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed. Cir. 2002). "The use of extrinsic evidence to construe the scope of a claim is improper where the ordinary and accustomed meaning of a claim term does not render the claim unclear and where the patentee has not chosen to be his own lexicographer." N. Telecom Ltd. v. Samsung Elecs., 215 F.3d 1281, 1288 (Fed. Cir. 2000). "While the Court may rely on expert testimony to understand the technology and the ordinary meaning of terms to practitioners in the art, expert testimony may not be used to contradict claim language or the specification." VLT Corp. v. Lambda Elecs., 238 F. Supp. 2d 347, 350 (D. Mass. 2003).

The Federal Circuit clarified the relationship between claim language and the specification in Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed. Cir. 2002), stating that "[c]onsulting the written description and prosecution history as a threshold step in the claim construction process,

before any effort is made to discern the ordinary and customary meanings attributed to the words themselves, invites a violation of our precedent counseling against importing limitations into the claims." The Federal Circuit emphasized that "dictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms," id. at 1202, for such sources "are objective resources that serve as reliable sources of information on the established meanings that would have been attributed to the terms of the claims by those of skill in the art," id. at 1203. However, "the intrinsic record also must be examined in every case to determine whether the presumption of ordinary and customary meaning is rebutted." Id. at 1204. "Further, the presumption also will be rebutted if the inventor has disavowed or disclaimed the scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Id. at 1203.

With these principles in mind, the Court turns to the questions of claim construction and infringement.

B. Claim Construction

1. "Immobilized"

Claim 5 requires "a second binder for capturing the ligand or the complex, the second binder being immobilized at the test site." Acon argues that its sandwich-type assays use a capture antibody as a binder at the test site that is not immobilized,

meaning "fixed or incapable of moving." Stedman's Med. Dictionary 852 (26th ed. 1995). In testing performed by Acon, up to 50 percent of the capture antibody moves out of the test sites and into the control zone in normal use. Acon argues that this percentage is too high for the binder to be "immobilized" within the meaning of the patent, for the patent requires that the test be able to perform a quantitative analysis, measuring the strength of a ligand in a liquid. (Aff. of Dr. Gary S. David of 9/15/2003 at ¶¶ 22-26.[4]) To achieve this level of precision, no "significant portion of the unlabeled specific protein binder can move out of the test site." (Id. at ¶ 24.) Therefore, in Acon's view, its products do not infringe, as a significant portion of the second binder can move out of the test site, and thus is not "immobilized." (Id. at ¶ 27 ("In Acon's ovulation test kit, the unlabeled antibody is also not equivalent to an 'immobilized' binder . . . because the movement of the capture antibody in Acon's ovulation test kit renders it unsuitable for quantitative analysis.").)

Inverness agrees that the term "immobilized" means "fixed or incapable of moving." However, it argues that claims 7 and 19 require merely the presence of second binders that are immobilized at the test site in sufficient quantity to "produce a

[4] Dr. David is a consultant to the biotechnology industry with over 30 years of experience in the field on both the research and business sides.

color visible to the unaided eye indicative of the presence of the ligand in the liquid," not that all of the molecules at the test site capable of binding with the conjugate be immobilized.

Turning first to the question of claim interpretation, the Court agrees that "immobilized" as used in the claim means "fixed or incapable of moving" with the passing liquid. With this definition, claim 5 only requires a second binder for capturing the ligand, which is immobilized at the test site, not that all of the binding agent at the test site be immobilized. The presence of other molecules that may bind with the ligand but be washed away does not defeat infringement, as long as there are second binders that are immobilized at the test site, and the "accumulation of colored particles at the test site produces a color visible to the unaided eye indicative of the presence of the ligand in the liquid."

Turning to the question of infringement, Acon argues that even under this claim interpretation there is no evidence of infringement, for Inverness has not proved that the second binder in Acon's devices is attached to the test strip.

The undisputed evidence shows that Acon's devices contain such immobilized "second binders." While Acon presented evidence that 8% to 50% of the binder at the test site is washed away, Inverness presented evidence that the remainder of the binders at the test site are immobilized, and indeed need to be in order for the test to work. (See Decl. of Dr. David F. Katz of 10/2/2003

at ¶ 9;[5] Decl. of Balbir Raj of 8/29/2003 at ¶¶ 16-18 ("If the antibodies were not immobile, and flow of the liquid sample caused the antibodies in the test zone to change their position relative to the strip material, then you could not be sure that a visible result would appear in the test zone.").) Additionally, Inverness submitted internal Acon product diagrams labeling hormones on the test and control lines as "immobilized." (Conf. Decl. of Anastasia M. Fernands of 10/3/2003 at Exhibit F.) Acon failed to provide evidence to support its suggestion that a sufficient number of unattached binders at the site can create a visual effect.[6] Given the testimony of Inverness's experts that in their experience the binders must be immobilized in order to function, and Acon's failure to provide evidence that a sufficient number of binders are not attached but still create a

[5] Dr. Katz is a Professor of Biomedical Engineering and Professor of OB/GYN at Duke University with 30 years of experience in the area.

[6] While Acon cites to David's affidavit in its brief, David provides primarily a legal argument. David argues first for Acon's incorrect claim interpretation, that the claim requires all of the second binder to be immobilized, and then applies the test results of Dr. Jinn-Nan Lin to show not all of the second binder is immobilized. Acon also offers the affidavit of Dr. Jinn-Nan Lin, who testifies that his experiment shows, *inter alia*, that in Acon's kits the test antibody is "diffusively attached," not "permanently attached," and therefore the antibody is not immobilized. Acon never clarifies what is meant by these terms ("diffusive" is not an antonym of "permanent" in common parlance), and this distinction is not pursued in briefing.

visual effect,[7] there is no genuine dispute of material fact that Acon's devices contain "immobilized" binders.

2. "Binder" as a means-plus-function element

Acon argues that most of its assays do not use "specific" binding proteins, proteins that bind to the target analyte and not to others, and so do not infringe. While Acon recognizes that the claims asserted by Inverness do not require a "specific" binder, it argues that the phrases "first binder for a ligand" and "second binder for capturing the ligand or the complex" are properly interpreted as means-plus-function elements under 35 U.S.C. § 112, ¶ 6, as they do not describe structures. If these are means-plus-functions elements, in Acon's view, the phrases are entitled only to the structural scope given in the specification, which describes a "specific" binder. See Lockheed Martin Corp. v. Space Sys./Loral, Inc., 324 F.3d 1308, 1320 (Fed. Cir. 2003) ("Literal infringement of a § 112, ¶ 6 claim requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification.").

"It is well settled that . . . a claim term that does not use [the word] 'means' will trigger the rebuttable presumption that § 112, ¶ 6 does not apply." Apex, Inc. v. Raritan Computer,

[7] The Court does not find credible Acon's argument that it does not know how its own products are manufactured.

Inc., 325 F.3d 1364, 1371 (Fed. Cir. 2003) (citing CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1369 (Fed. Cir. 2002)). "This presumption can collapse when a limitation lacking the term 'means' nonetheless relies on functional terms rather than structure or material to describe performance of the claimed function." Apex, 288 F.3d at 1372 (citing Micro Chem., Inc. v. Great Plains Chem. Co., 194 F.3d 1250, 1257 (Fed. Cir. 1999)). "As an aid in making this determination, this court inquires into whether the 'term, as the name for the structure, has a reasonably well understood meaning in the art,' keeping in mind that a claim term 'need not call to mind a single well-defined structure' to fall within the ambit of § 112, ¶ 6." Apex, 288 F.3d at 1372 (citing Greenberg v. Ethicon Endo-Surgery, Inc., 91 F.3d 1580, 1583 (Fed. Cir. 1996)). "The fact that a particular claim term is defined in functional terms is not sufficient to convert a claim limitation into a 'means for performing a specified function' within the meaning of 112(6)." Apex, 288 F.3d at 1372 (citing Greenberg, 91 F.3d at 1583). To make this determination, "the record should reflect the ordinary meaning of the claim limitations, as a whole, and whether these limitations suggest sufficiently definite structure to one of ordinary skill in the art." Apex, 288 F.3d at 1374. "In this situation, it is appropriate to look to extrinsic evidence, including but not limited to dictionaries and expert testimony to assist the trier of fact in understanding the evidence." Id. (citing Greenberg,

91 F.3d at 1583).

According to Acon, "a 'binder' does not have an established meaning to one of skill in the art." (Aff. of David of 10/17/2003 at ¶ 11.) Turning to the intrinsic evidence, Acon argues that the use of the terms "first binder" and "second binder" in the claims demonstrates the lack of structure indicated by the term "binder," as the same word refers to two different types of chemicals performing separate functions. Acon also argues that there are too many possible structures called to mind by the term "binder" to claim the invention with the particularity and distinctiveness required by 35 U.S.C. § 112(2). Finally, Acon argues against Inverness's use of a non-technical dictionary for the definition of binder (although it does not argue for a particular definition).

Noting that a means-plus-function test is limited to the structure disclosed in the specification, Acon argues that the specification describes the use of "specific" binders. "Specific" binders, according to Acon, are those that have "the ability . . . to distinguish the analyte of interest from other substances in a sample to be assayed." (Aff. of David of 10/17/2003 at ¶ 19.)

Certain (but not all) of Acon's products, by contrast, use binders that do not distinguish between the ligand and other substances; rather, the products use "a scavenger antibody that specifically binds to a possible interfering substance" (Aff. of

David of 9/15/2003 at ¶ 39) "to ensure that the overall assay is specific for [the desired ligand]." (Id. at ¶ 41). "Accordingly, the unlabeled and/or labeled antibodies used in Acon's pregnancy, ovulation and *H. pylori* test kits are not specific for their respective analyte." (Aff. of David of 10/17/2003 at ¶ 29.)

Acon has failed to overcome the presumption against means-plus-function construction in the case for a number of reasons. First, while claims 1, 2, 3 and 4 explicitly require as the immobilized binder, a "binder . . . . which specifically binds to the analyte" (see, e.g., '982 patent at 9:14-15 (Claim 1)), the patent claims at issue do not require any "specific" binder. Second, the technical dictionary definition of binder does not encompass a requirement of specificity. According to the McGraw-Hill Dictionary of Scientific and Technical Terms (1984), a "Binder" is: "a resin or other cementlike material used to hold particles together and provide mechanical strength or to ensure uniform consistency, solidification, or adhesion to a surface coating; typical binders are resin, glue, gum, and casein."

Third, Inverness's expert Dr. Katz states that a person of ordinary skill in the art would understand the phrase "binder for a ligand" as a structure, specifically "one or more possible structures, such as proteins or antibodies of various types, that will 'bind' with the ligand in an immunoassay which is used to

detect a ligand in a liquid sample." (Decl. of Katz of 10/2/2003 at ¶ 11.) Dr. David disagrees with Dr. Katz's opinion that a "binder for a ligand" would mean, to a person of ordinary skill in the art, anything with sufficiently definite structure. Thus, Dr. David states, "a 'binder' does not have an established meaning to one of skill in the art." (Aff. of David of 9/16/2003 at ¶ 31; Aff. of David of 10/17/2003 at ¶¶ 10-11.)

While the structure of the binder might well vary depending on for which ligand the test was intended, the use of the term "binder" is not a function even though it might not call to mind a single well-defined structure. Using the plain meaning of the claim, the Court concludes that one of ordinary skill in the art would understand "binder" for a ligand as used in the patent to mean a composition of matter that is capable of binding to a ligand. The Court does not construe the term "binder for a ligand" to require a protein that "specifically" binds with a ligand; therefore, Acon's devices infringe regardless of whether they use specific binders.

3. Number of steps in claim 7

Acon argues that claim 7 allows for a two-step or "pre-mix" process, in which the liquid suspected of containing a ligand is mixed with the conjugate in a separate container or test tube before being added to the test strip. Under this interpretation, Acon argues, claim 7 was anticipated by Brooks I

and Brooks II, which date back to the June 9, 1986 date of the application filed by Mochnal.[8] Acon makes two arguments to support this claim: first, that the language of dependent claim 7, "wherein the conjugate is in dry form," does not specify that the conjugate must be in dry form on the test strip, and so allows for it to be in dry form in a separate test tube; and second, that the definition of a "flow path" that is "extending from a sample application site to at least a test site" is broad enough to include a test tube.

(a) Dry form

As to the first, Acon argues that the language of claim 7, "the test device of claim 6 wherein the conjugate is in dry form," does not specify when the conjugate must be in dry form.[9] Acon argues that the conjugate therefore could be in dry form in a test tube, as per the first several uses of "conjugate" in claim 5, and then added to the test device. Acon claims that courts should not impose a sequential order on claim steps that do not themselves create an order, citing Union Oil Co. of Cal. v. Atl. Richfield Co., 208 F.3d 989, 992 (Fed. Cir. 2000). Acon points out that the conjugate cannot be in dry form in each step

[8] The parties disagree whether Brooks I and Brooks II can claim priority to the Mochnal filing date.

[9] Claim 5, the independent claim, was listed above. Claim 6 provides: "The test device of claim 5 wherein the conjugate is disposed in the flow path upstream of the test site and is mobilizable along the flow path with passing liquid."

of claim 5, for one of the steps mentions that it is mixed with liquid. As support for this reading, Acon points to passages from the prosecution history that it argues shows that David Charlton, the named inventor, argued that these claims are broad enough to cover both pre-mix and pee-on embodiments.

Here, the language of claims 5-7 makes it clear that claim 7 is intended to cover a dried-on embodiment. The language "mobilizable along the flow path with passing liquid" in claim 6 indicates that the "dried on conjugate" of claim 7 is to be "disposed in the flow path." If it were already mixed with liquid, then it would already be mobilized, not mobilizable, and the liquid would not be "passing," but rather would be part of the conjugate. Additionally, claim 5 specifies that the flow path is part of the "test strip," so that a conjugate on the "flow path" could not be in a test tube. Read in context, the plain meaning of claim 7 is that the conjugate is to be in dry form while disposed in the flow path.

The Court must still examine "if the inventor has disavowed or disclaimed the scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Texas Digital, 308 F.3d at 1203. In the prosecution history, the applicant stated that he did not consider the use of a "dried on" embodiment to be part of his invention for the purposes of establishing a reduction to practice (and hence priority over U.S. Patent No. 5,120,643

(issued June 9, 1992) ("Ching")). Specifically, during the prosecution of the parent to the '982 patent, the applicant stated: "Whether the mixture is produced by physically mixing the two before the reactants are applied to the test strip, or alternatively are mixed as sample picks up dried conjugate on the strip, is not relevant to the claimed invention."

This statement is not a clear disavowal of the scope of the claims: the applicant was arguing that the dried-on embodiment was obvious in light of the pre-mix embodiment, and so he should not have to show a separate reduction-to-practice. Therefore, the prosecution history does not compel a different claim interpretation, and claim 7 refers to a one-step process, for the "wherein the conjugate is in dry form" language refers to the conjugate being in dry form when disposed in the flow path upstream of the test site.

(b) Test tube as a "flow path"

Acon makes a less-plausible argument in one of its reply briefs that the "flow path" can include a test tube, for the flow path can be defined as "extending from a sample application site [in the test tube] to at least a test site." Acon notes that claim 5 includes the word "comprising," and points to prosecution history to support its point.

This argument is not persuasive. Inverness correctly points out that claim 5 reads: "a test strip comprising a sorbent material defining a flow path." A test tube is not a sorbent

material, for it does not "sorb." See Random House Webster's College Dictionary 1277 (1992) (defining "sorb" as "to gather on a surface either by absorption, adsorption, or a combination of the two processes"). As a matter of claim interpretation, the flow path must be a sorbent material, and a test tube cannot be part of the "flow path." Pointing to the term "comprising" also does not help Acon, for while it would allow additional elements on the "test strip," it is not used in reference to the "flow path."

The prosecution history also does not support Acon's position. The language of claims 40 and 41 then at issue differed in relevant part from the claims at issue here. While Charlton did argue that claims 40 and 41 of a prior application did not require a single piece of material, in the passage quoted by Acon he explicitly distinguished those broader claims from claims that require "lateral flow along an elongate, one-piece test strip." (David Aff. of 12/15/2003, Ex. 29 (Charlton Reply before Board of Patent Appeals, Patent Interference No. 104,148, May 3, 2000) at 7 (emphasis in original)). The claims at issue, however, require a "test strip."

Finally, in context, Charlton was not disavowing scope, but rather trying to expand coverage. Charlton was arguing that his specification supported claims beyond those that were side-by-side in a "lateral" arrangement on a single strip, and also covered a test device not in the same plane or even on the same

piece of matter. Therefore, the prosecution history does not change the meaning of terms, and claim 7 covers a dried-on, one-step process only.[10]

C. Validity

1. Presumption of Validity

A patent, and each one of its individual claims, is statutorily presumed to be valid. 35 U.S.C. § 282. However, the "presumption [of validity] is weakened where the most pertinent prior art was not considered by the Patent Office." Nossen v. United States, 416 F.2d 1362, 1371 (Ct. Cl. 1969). In addition to the statutory presumption, "a claim must be construed to uphold its validity if possible." Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987) (holding that inclusion of the word "only" in the clause of a patent's claim limitation saved a later patent from invalidation by anticipation, as the word "only" could not be read out of the prior patent's claim).

While 35 U.S.C. § 282 assigns the burden of establishing a patent's invalidity to the challenger, the Federal Circuit has declared that "at the preliminary injunction stage, because of the extraordinary nature of the relief, the patentee carries the burden of showing likelihood of success on the merits with

[10] This reading makes further consideration of arguments pertaining to anticipation by Brooks I and Brooks II unnecessary.

respect to the patent's validity." Nutrition 21, 930 F.2d at 869. In other words, the patentee "retain[s] the burden of showing a reasonable likelihood that the attack on its patent's validity would fail." H.H. Robertson Co. v. United Steel Deck, Inc., 820 F.2d 384, 387 (Fed. Cir. 1987). This burden requires the patentee to make a "clear showing" that the challenger would be undermined. Atlas Powder Co. v. Ireco Chemicals, 773 F.2d 1230, 1233 (Fed. Cir. 1985). "While it is not the patentee's burden to prove validity, the patentee must show that the alleged infringer's defense lacks substantial merit." Id.

2. Anticipation

"A person shall be entitled to a patent unless . . . the invention was described in a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent." 35 U.S.C. § 102(e). "Anticipation under 35 U.S.C. § 102 requires the presence in a single prior art disclosure of each and every element of a claimed invention." Lewmar Marine, 827 F.2d at 747.

Acon claims that claims 5, 6, 7 and 18 of the '982 patent were anticipated by several prior patents:[11] Ching (previously defined as U.S. Patent No. 5,120,643 (issued June 9, 1992)); and

[11] Acon has not pressed its anticipation argument with respect to the Graham Patent, U.S. Patent Application No. 872,355 (filed June 9, 1986), against claims 7 and 19. Therefore, I do not address the Graham patent anticipation argument, which was first raised in the preliminary injunction papers.

U.S. Patent Application No. 872,357 (filed June 9, 1986) ("Mochnal").[12] Inverness responds that the immunoassays presented in these patents lack, among other elements, the presence of a dried conjugate mobilizable in the flow path, and Ching, in addition to lacking other elements of the '982 patent, is not prior art.

(a) Brooks/Mochnal

Acon claims that Brooks and Mochnal anticipate claim 7 (but not claim 19). Brooks describes a two-step sandwich array in which a gold labeled antibody is dried in a test tube and pre-mixed with a urine sample. One end of a test strip is dipped into the mixture. The mixture is transported along the test strip by capillary action to a test line containing a "immobilized" capture antibody.

Neither the Brooks patent nor the Mochnal application discloses the use of a conjugate dried in the flow path that is mobilizable by the flowing of liquid, as required by claim 7. Acon argues that under the plain meaning of claim 7, the limitation "wherein the conjugate is in dry form" includes a

[12] As noted earlier, the parties variously refer to the Brooks Patent and Mochnal application. The Brooks Patent was granted on the basis of a continuation-in-part application that Brooks filed in November, 1989, a year after Charlton filed the original application. Acon argues that the Brooks patent has priority back to a June, 1986 application filed by Mochnal, and also points to another patent Brooks II for anticipation. The parties dispute this murky point, which luckily I need not resolve.

conjugate that is dry at any point. As pointed out in the claim construction section, the Court disagrees with that construction. In any event, even if Acon were correct, it concedes that claim 19 expressly limits the location ("[T]he conjugate is dried in the flowpath upstream of the test site.") and requires that the conjugate be dry before the sample is applied ("[T]he liquid sample is applied upstream of the dried conjugate.").

Acon also argues that in a prior patent litigation, Inverness Medical Switzerland GMBH v. Pfizer Inc., No. 02-1029 (D.N.J.), Inverness had argued that the term "dry porous carrier" encompasses both wet and dry forms of the carrier, as the carrier becomes wet when it is in use; therefore, Acon reasons, the "dried conjugate" must encompass both dry and wet conjugates. Acon presumably argues that because Mochnal discloses a wet conjugate, it anticipates the '982.

Only a patent lawyer could argue with a straight face that dry means wet. Acon's argument contradicts the plain language of the claim. Acon fails to provide any intrinsic or extrinsic evidence that a dried conjugate is the same as a wet conjugate. Therefore, Brooks and Mochnal do not anticipate claims 7 and 19 of the '982 patent.[13]

(b) Ching

Turning to Ching, Acon argues that Ching predated the '982

[13] Because Mochnal clearly does not anticipate claim 7 or claim 19, the Court does not address claims 5,6 and 22.

patent's priority date of September 23, 1986, which Charlton was able to establish in an unrelated interference proceeding between Charlton and Rosenstein. Acon offers an affidavit stating that Ching told an attorney via telephone that he believed that he had reduced his invention to practice by late December of 1986, three months later. Acon states that inventors typically conceive of their inventions some time before they reduce them to practice. Acon is, at best, guessing that Ching may have been earlier. The Court finds that Acon is not likely to be able to overcome the presumption of validity to prove that Ching predated September 23, 1986.

Acon also assails the September 23, 1986 date that the PTO established as incorrect in light of the evidence, or at least incorrect for claim 19.[14] Acon argues that the experiment performed by Mazzeo did not involve applying the liquid "upstream of the dried conjugate" as required by claim 19, but that the sample liquid was applied directly onto dried labeled antibody. Asserting that Mazzeo's new affidavits and Charlton's affidavit contradict Mazzeo's earlier statements, Acon highlights a 1997 declaration by Mazzeo in which she stated, "I pipetted a liquid sample onto the disks until the disks and the strips had been saturated with the liquid sample," and a page from her notebook

[14] Acon does not argue in its briefs that Ching predated claim 7, which does not contain the "upstream" language. While Acon mentioned at hearing that Ching would apply to claim 7, it did not explain how.

as support. Acon claims that the Court must disregard Mazzeo's later testimony as being untrustworthy, and argues that there was insufficient corroboration of the September 26 date.

Plaintiffs respond with affidavits from Charlton and Mazzeo in which they state that the liquid sample was pipetted onto the disk through a cigarette filter, which was upstream of the dried conjugate. These affidavits also point to testimony from 2000 supporting this version of events. Mazzeo also points out that she mentioned a cigarette filter in her 1997 testimony, and that it was listed on that page from her notebook. Plaintiffs note that the lab notebook and other documents provide corroborating evidence, and that the Mazzeo testimony itself was corroborating evidence, not the sole evidence. While Acon correctly points to a potential discrepancy, the later affidavits do not hem and haw. The documentary evidence supports the position that a cigarette filter was used, so there is contemporaneous support for Mazzeo's later declarations. Therefore, Plaintiffs have shown that they have a likelihood of undermining Acon's arguments on this issue with respect to claim 7, although the facts are disputed.

3. Obviousness

Although Acon has not moved for summary judgment on the issue of obviousness, it contends that Inverness has not established a likelihood of success on the defense. Under 35 U.S.C. § 103(a),

[a] patent may not be obtained though the invention is

> not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Obviousness under § 103 is a legal conclusion based on underlying factual inquiries, including: a) the scope and content of the prior art; b) the level of ordinary skill in the art; c) the differences between the claimed invention and the prior art; and d) objective evidence of nonobviousness. See Graham v. John Deere Co., 383 U.S. 1, 15, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966). When patent claims have been upheld in a reexamination proceeding before the PTO in which much the same prior art was presented, the burden upon the party asserting invalidation for obviousness is made heavier. See Custom Accessories, Inc. v. Jeffrey-Allan Indus., 807 F.2d 955, 961 (Fed. Cir. 1986).

When making an obviousness analysis based on prior art teachings, reviewing courts must not fall prey to a "hindsight syndrome," reasoning backward from the teaching of the patent itself. See In re Kotzab, 217 F.3d 1365, 1369 (Fed. Cir. 2000). According to the Federal Circuit, "the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." In re Gartside, 203 F.3d 1305, 1319 (Fed. Cir. 2000); see also B.F. Goodrich Co. v. Aircraft Braking Sys. Corp., 72 F.3d 1577,

1582 (Fed. Cir. 1996). In other words, something in the prior art, considered as a whole, must "suggest the desirability, and thus the obviousness, of making the combination" of different elements to create the invention. Fromson v. Advance Offset Plate, Inc., 755 F.2d 1549, 1556 (Fed. Cir. 1985) (citing Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick, 730 F.2d 1452, 221 U.S.P.Q. 481, 488 (Fed. Cir. 1984)).

Acon argues that the '982 is obvious in light of 1) Graham and in light of 2) the combination of Mochnal and EP 0,170,375 A2 (publ. Feb. 5, 1986) ("EP 375"). Meanwhile, Acon's expert, Dr. David, argued additionally in his first affidavit that the '982 was obvious in light of 3) Graham combined with EP 375, as well as in light of 4-5) EP 0,149,168 A1 (publ. July 24, 1985) ("EP 168") or U.S. Patent No. 4,861,711 (issued Aug. 29, 1989) (the "'711 patent") combined with U.S. Patent No. 4,373,932 (issued Feb. 15, 1983) (the "'932 patent") or H. van Hell et. al, Particle Immunoassays, in Alternative Immunoassays 34-57 (Collins, H.W.P. ed., 1985) ("Collins"). The Court holds none of them sufficient to demonstrate an ability to overcome the presumption of validity.

Given Inverness's argument that the Court need look only to claims 7 and 19 to find validity for the purposes of the present motion, the issue of obviousness comes down to whether 1) Graham alone makes the '982 obvious; 2) adding EP 375 onto Graham or Mochnal teaches the '982 patent; and 3) whether any combination

of the other four patents renders the '982 patent obvious.

The Court concludes that Graham alone does not suffice to make the '982 patent obvious. Dealing only with the issue of the "dried conjugate," Graham nowhere hints at the benefits that would be obtained by the use of a dried conjugate, and Acon has failed to provide evidence that one of ordinary skill in the art at the time would find the '982 obvious in light of Graham. Acon's brief cites to Dr. David's opinion, paragraphs 59-61 for the proposition that using a dried conjugate is obvious in light of Graham, but Dr. David does not so state. Rather, he states that one must look to EP 375 for the teaching of a dried conjugate.

Setting aside the question of whether Graham or Mochnal teach other elements of the '982 patent, the question becomes whether EP 375 in combination with Graham or Mochnal teaches the use of a conjugate dried in the flow path to obtain the same results. EP 375, entitled "Devices for Use in Chemical Test Procedures," teaches a method of:

> [a] specifically-reactive sample-collecting and testing device possessing a cavity or cavities each having a dimension small enough to enable sample liquid to be drawn into the cavity by capillary action, wherein said cavity includes an electrode structure for making measurements of one or more electrically measurable characteristics of the sample, and wherein a surface of a wall of the cavity optionally also carries a coating of a material appropriate to the test to be carried out in the device.

EP 375 at cover, ¶ 57. In lay terms, "EP 375 describes a device

that has two solid plates or 'sheets' (for example, made of glass) between which the liquid sample flows . . . . The device in EP 375 tests for various analytes by measuring changes in an electric current that is being run through electrodes attached to one of the plates." (Decl. of Michael E. Prior of 10/2/2003 at ¶ 13.[15])

Notably, EP 375 states that "[e]specially in the case of impedance-measuring devices, the area between two electrodes on one wall of the cell can be coated with a specific binding agent which can bind conducting particles such as gold sol particles as used in certain immunoassays." EP 375 at 12:11-15. Also, "[i]n general, thin coating layers of biochemical reagents can be present; they can be either immobilized (i.e. non-releasable) or releasable coatings, e.g., formed by air-drying protein-sucrose mixtures in thin films on the plates." EP 375 at 16:30-35. Finally, EP 375 provides that "[i]f desired, at least one of the walls surrounding the cavity can be transparent to light, e.g. to visible and/or ultraviolet light, with optically regular, generally smooth surfaces, so as to enable photoelectrical measurements and/or optical analysis in situ of the products of the sample collection and reaction with the specific binding capacity, as well as the electrical measurements enabled by the

[15] Michael Prior is a product development scientist formerly working for Plaintiffs who has over 30 years of experience in the field.

electrode(s)." EP 375 at 8:33 to 9:4.

Thus, EP 375 discloses the method of drying certain reagents on the surface in which the test is to be run, discloses the use of gold sol particles in making a test, and discloses the possibility of allowing for a visual analysis of the results in addition to an electrical analysis. However, EP 375 does not disclose drying gold sol particles to obtain a visual result, as opposed to attempting to obtain conductivity that can be measured electrically.

There is a genuine dispute of material fact concerning whether it would have been obvious to combine EP 375 with either Graham or Mochnal to produce the '982 patent. According to Mr. Prior, "[h]aving a conjugate in a dried form along the flow path upstream of the test site is critical because it means that the test can be formatted into a one-step device where all the necessary regents are dried onto the test strip, and all that is needed for the test to operate is the addition of the liquid sample." (Decl. of Prior of 10/2/2003 at ¶ 10.) By way of contrast, "[m]ultiple step devices such as Graham's are not user-friendly. The number of steps required to run the test and the need to measure and separately apply the sample and conjugate make the test more difficult to run successfully and increase the risk of user error." (Id. at ¶ 11.) EP 375 has certain elements present disparately that are also present in the '982 patent. However, Acon has not shown that it has a likelihood of success

in proving that the two-step devices of Graham and Mochnal, combined with the multi-step, electrical testing device of EP 375, would render obvious the one-step, visual process of the '982 patent, which is made possible by drying conjugates in the flow path. The drying, gold sol, and visual results elements in EP 375 are not connected in any way in EP 375 such that without the benefit of hindsight it would have been obvious as a matter of law to apply them to Mochnal or Graham.

There is also a dispute as to whether there would have been a motive to combine the references. Mr. Prior testified that the EP 375 does not add "anything to Graham that would lead one to develop a lateral flow device as claimed in the '982 patent, particularly since the device in EP 375 works in such a fundamentally different way than either the devices disclosed in Graham or the '982 patent." (Decl. of Prior of 10/2/2003 at ¶ 14.) Acon states that the motive to combine results because "it was generally known that eliminating unnecessary step [sic] in an assay procedure can lead to quicker assay results and less opportunities of introducing errors in the assay." (David Aff. of 10/17/2003 at ¶ 47.) That may be true, but nowhere in EP 375 is there a clear indication that the drying of certain proteins is a step-saving maneuver, much less that one could dry gold sol in order to avoid a step. Additionally, the revelations of EP 375 are of a different nature from those of Graham and Mochnal. EP 375 is a device for measuring the presence of chemicals

through the use of two plates and electrical measurement; Graham and Mochnal reveal multi-step immunoassay devices intended to provide convenient and simple tests.

The remaining question on obviousness is whether the '982 patent is obvious in light of the four other patents cited by Dr. David. Inverness responded to this argument by providing testimony that the '711 patent and EP 168 fail to disclose the use of colored particulate labels, and "it historically proved much more difficult to develop immunoassays using particulate labels embedded or dried onto a test strip because such drying caused the particles to stick in the porous test strip, thus preventing them from mobilizing and flowing down the strip with the urine." (Decl. of Prior of 10/2/2003 at ¶ 16.) The Collins and the '932 patent, Mr. Prior testifies, use colloidal dye particles within aqueous mediums, not dried onto test strips. (Id. at 20.) According to Mr. Prior, because of the difficulty of "drying particulate labels into a test strip and then reconstituting them with the liquid sample in such a way that they flow downstream to the test site," it would not be obvious to combine these references to result in the '982 patent. (Id. at ¶ 23.)

Inverness cites the decision of the PTO's Board of Patent Appeals in an interference proceeding relating to the '982 patent, dealing with similar prior art references, for the proposition that the use of dried conjugate particles was not

obvious:

> We have not been able to find in the pour-on embodiment, Cerny and Deutsch, or any other prior art called to our attention, the necessary suggestion to combine the teachings of the prior art to arrive at the embedded particle embodiment. It may be true that the embedded particle embodiment seems simple, at least after the fact. But, we decline to equate simplicity with obviousness. Many inventions seem simple after the fact. It is our opinion, that one arrives at the embedded particle embodiment, based on the prior art called to our attention, solely on the basis of impermissible hindsight. Hence, we hold that Rosenstein has sustained its burden of proof.

(Non-conf. Decl. of Fernands, Ex. B at 24-26 (Charlton v. Rosenstein, proceeding before Board of Patent Appeals and Interferences, Patent Interference 104,148 (March 8, 2000)).)

Based on the decision of the Board of Patent Appeals and Interferences, the Court finds that Inverness has shown a likelihood of defeating this challenge by Acon, although the obviousness defense cannot be resolved on summary judgment.

4. Best Mode

The best mode requirement of 35 U.S.C. § 112 states that a patent specification "shall set forth the best mode contemplated by the inventor of carrying out his invention." "The purpose of the best mode requirement is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of the inventions they have in fact conceived." Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d

1313, 1330 (Fed. Cir. 2002). To mount a best mode challenge under the two-pronged test established by the Federal Circuit, a party must demonstrate that (1) an applicant knew of "specific instrumentalities or techniques which are recognized at the time of filing as the best way of carrying out the invention," Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1532 (Fed. Cir. 1987); and (2) those specific instrumentalities or techniques were not "adequately disclosed." Id. at 1536. The first inquiry is subjective and requires the Court to look at the state of mind of the inventor at the time that the patent application was filed to see if the inventor considered "an alternative mode superior to the disclosed mode." Minco, Inc. v. Combustion Eng'g, Inc., 95 F.3d 1109, 1115 (Fed. Cir. 1996) ("[T]he inventor's intent controls."). The second inquiry is objective. Fonar Corp. v. General Electric Co., 107 F.3d 1543, 1548 (Fed. Cir 1997). "[T]he factfinder must determine whether the best mode was disclosed in sufficient detail to allow one skilled in the art to practice it." Id. at 1548. Failure to find intentional concealment does not preclude a violation, for accidental concealment can also lead to a best-mode violation. United States Gypsum Co. v. National Gypsum Co., 74 F.3d 1209, 1215-16 (Fed. Cir. 1996).

Acon argues that claims 7 and 19 are invalid under the best mode requirement because Charlton did not specify what buffer he was using. As support, Acon points out that in several documents

describing the experiment used to establish the reduction to practice date, Mazzeo or Charlton name the specific buffer they used, which was developed by Carter-Wallace, the company developing the '982 patent. Acon argues that the article cited by the specification as providing information about buffers was not incorporated by reference, could not serve as a substitute for naming a buffer even if it were, and did not contain information about the particular buffer that Charlton used.

Plaintiffs respond with an affidavit from Charlton stating that he did not believe that the buffer solutions used by Mazzeo were the best mode of practicing his invention, and he and Mazzeo were in fact experimenting with several different types of buffers, all of which were known to those of ordinary skill in the art. Charlton states that any of those buffers could be used to practice the invention. Plaintiffs also refer to 8:27-30 of the '982 patent, which states: "Additional details of the currently preferred procedure for making the antibody sol conjugate are disclosed by Leuvering et al, J. Immunoassay (1980) supra." Plaintiffs claim that this article discloses several different buffer solutions.

The evidence is disputed as to whether Charlton thought of one buffer as the "best mode" to impeach his affidavit, but under the evidence presented Inverness has a strong likelihood of success. The evidence shows that Charlton was experimenting as late as 1997 with various buffers. The fact that he and his

assistant used one buffer does not necessarily indicate that he believed that buffer was the best, especially in light of his affidavit stating that he had no such belief.

D. Inequitable Conduct

"In order '[t]o prove inequitable conduct in the prosecution of a patent, [the defendant] must have provided evidence of affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive.'" Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1362 (Fed. Cir. 2003) (citing Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1366 (Fed. Cir. 2001)). "Both intent and materiality are questions of fact that must be proven by clear and convincing evidence." Id. In making this inquiry, a court makes "first, a determination of whether the withheld reference meets a threshold level of materiality and intent to mislead, and second, a weighing of the materiality and intent in light of all the circumstances to determine whether the applicant's conduct is *so culpable* that the patent should be held unenforceable." Id.

For many years, the applicable standard for materiality of prior art in an inequitable conduct claim was whether "a reasonable examiner would have considered such prior art important in deciding whether to allow the parent application." Dayco, 329 F.3d at 1363. The Federal Circuit has not decided

whether this standard still applies in light of the amendment made by the Patent Office to its rules that "more narrowly defined materiality, providing for disclosure where the information establishes either 'a prima facia case of unpatentability' or 'refutes, or is inconsistent with a position the applicant takes.'" Id. at 1363-64 (citing 37 C.F.R. § 1.56 (1992)). Cf. Ulead Sys., Inc. v. Lex Computer & Mgt. Corp., 351 F.3d 1139, 1144-45 (Fed. Cir. 2003) (holding that new PTO fraud rule applicable to "small entity status" did not establish standard different from inequitable conduct caselaw).

Information about foreign patents can be material prior art. See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 (Fed. Cir. 1995) (citing provision of Manual of Patent Examining Procedure providing that "[a]pplicants . . . have a duty to bring to the attention of the Office any material prior art or other information cited or brought to their attention in any related foreign application. The inference that such prior art or other information is material is especially strong where it is the only prior art cited or where it has been used in rejecting the claims in the foreign application"). Courts should be "mindful of the risk in relying on foreign patent prosecution in light of differences in disclosure requirements, claim practice, form of application, and standard of patentability." Id. Details of foreign prosecutions, as opposed to the prior art references cited therein, do not generally constitute an independent

category of material information. ATD Corp. v. Lydall, Inc., 159 F.3d 534, 547 (Fed. Cir. 1998) ("Although international search reports may contain information material to patentability if they contain closer prior art than that which was before the United States examiner, it is the reference itself, not the information generated in prosecuting foreign counterparts, that is material to prosecution in the United States. The details of foreign prosecution are not an additional category of material information.").

"Intent [to mislead] need not be proven by direct evidence; it is most often proven by a showing of acts, the natural consequences of which are presumably intended by the actor." Molins, 48 F.3d at 1180. "Generally, intent must be inferred from the facts and circumstances surrounding the applicant's conduct." Id. While actions such as "'burying' a particularly material reference in a prior art statement containing a multiplicity of other references can be probative of bad faith," id. at 1184, "'intent to deceive should be determined in light of the realities of patent practice, and not as a matter of strict liability whatever the nature of the action before the PTO,'" id. (quoting N. Telecom, 908 F.2d at 939).

Acon claims that Inverness engaged in inequitable conduct by failing to bring to the attention of the examiner for the '982 patent the fact that the European Patent Office ("EPO") revoked the '982 European counterpart for lack of an "inventive step."

The EPO revoked the European counterpart on November 24, 1998, referring to a combination of four references as making the invention unpatentable. As evidence of intent to deceive, Acon points to a prior request by the patent examiner for information regarding European patents in light of the over 200 prior art references made in the '982 patent.

Inverness responds that the four pieces of prior art relied upon by the EPO were before the patent examiner (who made the request for more information in 1996, two years prior to the EPO revocation), that the examiner knew of the existence of the foreign revocation proceedings, and that its patent prosecutor knew that the details of foreign patent prosecutions need not be disclosed to the PTO in light of ATD, which had been published several weeks before the EPO decision. Inverness also points out that the examiner asked applicants to "comment on the materiality of each of the cited documents which derived from multiple patent proceedings," which he then specified, and that his request had nothing to do with EPO's revocation proceedings. (Nixon Decl., Ex. B at 8.)

Acon replies that it was unreasonable to expect the patent examiner to come up with the same combination of four references used by the EPO in light of the over 200 references provided, and that ATD did not address the situation of a foreign rejection, but rather addressed the less-significant situation of foreign prosecution records relating to one specific reference.

In light of the evidence provided, Acon is likely to be able to show by clear and convincing evidence that revocation of the European counterpart because of the combination of four prior references was material. A reasonable patent examiner would have considered information that a combination of four prior art references invalidated the patent in Europe, especially in light of the fact that the examiner had previously requested assistance in dealing with the extremely large number of prior art references. Cf. Dayco, 329 F.3d at 1367 (holding that "a contrary decision of another United States examiner reviewing a substantially similar claim" meets the "reasonable examination threshold materiality test").

However, Acon has not demonstrated an ability to prove the requisite intent by clear and convincing evidence. The evidence provided could support an inference that the patent prosecutor intended to overwhelm the PTO with the sheer number of references, and did not disclose the revocation decision by the EPO despite its materiality and the examiner's requests for assistance out of a belief that such decision would prompt the examiner to combine the key references. However, such an inference does not rise to the level of "clear and convincing" proof. Given the lack of clear caselaw requiring an applicant to disclose an adverse decision by a foreign patent examiner and the basis for it, and the lack of evidence concerning the relevance of the prior art references (for example, was it a crowded

field?), the evidence presented could also support an inference that the patentee believed the prior art references to be sufficiently before the examiner, and the details of the foreign prosecution to be extraneous and nonmaterial. Thus, at this stage, Inverness has met its burden of showing a likelihood of success on this point. However, a trial will be necessary to resolve the issue.

E. Written Description

Acon argues that the '982 fails to meet the requirements of 35 U.S.C. § 112, ¶ 1, which provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

Acon points out that the parent application to the '982 patent required that the test strip be within a "casing," and that it was argued during the prosecution of the parent patent that the casing was a key component of the invention that distinguished it from prior art.

The statutory language mandates that an applicant must "both describe the claimed invention adequately and enable its reproduction and use." Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1330 (Fed. Cir. 2003) (quoting Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991)). "The purpose of the written description requirement is to prevent an applicant

from later asserting that he invented that which he did not; the applicant for a patent is therefore required to 'recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'" Id. "Satisfaction of this requirement is measured by the understanding of the ordinarily skilled artisan." Id. (quoting Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997)). "Compliance with the written description is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" Id. (quoting Enzo Biochem v. Gen-Probe, Inc., 296 F.3d 1316, 1324 (Fed. Cir. 2002)).

In discussing the written description requirement, the Federal Circuit has recently reiterated "the settled principle that a broadly drafted claim must be fully supported by the written description and drawings." Amgen, 314 F.3d at 1333 (noting though that "we did not announce [in Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473 (Fed. Cir. 1998)] a new 'essential element' test mandating an inquiry into what an inventor considers to be essential to his invention and requiring that the claims incorporate those elements"). "[A] broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope." Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc., 291 F.3d 1317, 1323 (Fed. Cir. 2002); Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319-20 (Fed. Cir. 2003) (quoting In re

Wright, 866 F.2d 422, 424 (Fed. Cir. 1989) for the proposition that "[w]hen the scope of a claim has been changed by amendment in such a way as to justify an assertion that it is directed to a different invention than was the original claim, it is proper to inquire whether the newly claimed subject matter was described in the patent application when filed as the invention of the applicant. That is the essence of the so-called 'description requirement' of § 112, first paragraph").

The Court ought not to focus on whether the exact same terms are used, for "[i]n order to comply with the written description requirement, the specification 'need not describe the claimed subject matter in exactly the same terms as used in the claims; is must simply indicate to persons skilled in the art that as of the filing date the applicant had invented what is now claimed.'" All Dental Prodx, LLC v. Advantage Dental Products, Inc., 309 F.3d 774, 779 (Fed. Cir. 2002) (quoting Eiselstein v. Frank, 52 F.3d 1035, 1038 (Fed. Cir. 1995)). However, "[t]he question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention." Turbocare Div. of Demag Delaval Turbomachinery Corp. v. General Electric Co., 264 F.3d 1111, 1119 (Fed. Cir. 2001) (quoting Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997)).

Acon argues that the parent application to the '982 required that the device contain a "casing," and that by deleting this

limitation Charlton violated the written description requirement. Acon mentions that during the prosecution of the patent prior art was repeatedly distinguished on the basis of the casing feature. Acon cites to the affidavit of Dr. David, who argues that the prosecution history shows that Charlton was not in possession of a device without the casing and that Charlton considered the casing essential. Acon's argument is that the Court must make "an inquiry into what an inventor considers to be essential to his invention [the casing] and requir[e] that the claims incorporate those elements," a test explicitly rejected by the Federal Circuit. Amgen, 314 F.3d at 1333.

Acon has not demonstrated a violation of the written description requirement because the original specification fully disclosed the making of the product in the '982 patent. The casing was an extra feature pursued at the time but not present in the '982 patent. In other words, Inverness was claiming less than it discovered in the test strip within the casing. Inverness supports its arguments with the affidavits of Dr. Katz and Michael Prior, each of whom has over 30 years of experience in the field. Prior and Katz both state that one skilled in the art at the time would clearly understand that one can perform the invention without the casing, although the casing provides additional useful benefits. (Prior Decl. of Nov. 27, 2003 at ¶ 8; Katz Decl. of Dec. 5, 2003 at ¶ 7.)

For these reasons, Plaintiffs have shown a likelihood of

success on the issue, and Acon's motion for summary judgment on the issue is **DENIED**.

F. Irreparable Harm

Where the patentee makes a clear showing of likelihood of success on infringement and validity, it is entitled to a presumption of irreparable harm. Roper Corp. v. Litton Sys., Inc., 757 F.2d 1266, 1271 (Fed. Cir. 1985). The Federal Circuit has noted that "it must be not merely a reasonable but a strong showing indeed," id., since this relief is a "drastic and extraordinary remedy that is not to be routinely granted," Intel Corp., 995 F.2d at 1568. "Like most legal presumptions, it is rebuttable by clear evidence that it is overcome in the case at hand." Id. To overcome the presumption, the alleged infringer must "bring forward evidence that irreparable injury would not actually be suffered by the patentee if the motion for preliminary injunction were denied." Id.

The Federal Circuit has stated that the presumption may be rebutted by showing, for example, "that (1) the non-movant has or will soon cease the allegedly infringing activities . . . thus making an injunction unnecessary; (2) movants have engaged in a pattern of granting licenses under the patent . . . such that it may be reasonable to expect that invasion of the patent right can be recompensed with a royalty rather than with an injunction; or (3) movants unduly delayed in bringing suit, thereby negating the

idea of irreparability." Polymer Techs., Inc. v. Bridwell, 103 F.3d 970, 974 (Fed. Cir. 1996).

Here, particularly in light of the opinion issued by the Board of Patent Appeals, Inverness has demonstrated the requisite clear, strong showing of a likelihood of success on the merits to warrant the presumption of harm, which Inverness has failed to rebut. While Inverness waited ten months before bringing suit, "[p]icking off one infringer at a time is not inconsistent with being irreparably harmed," Polymer, 103 F.3d at 975, and Acon has not shown that the delay was unreasonable.

G. Balance of Hardships

In considering the balance of hardships, "[t]he magnitude of the threatened injury to the patent owner is weighed, in the light of the strength of the showing of likelihood of success on the merits, against the injury to the accused infringer if the preliminary decision is in error." H.H. Robertson, 820 F.2d at 390. If a plaintiff will ultimately prevail at trial, then any harm befalling the defendant is its own doing. Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 708 (Fed. Cir. 1997) (stating that harm to the defendant was not relevant because it had no right to infringe on the plaintiff's patent). "[O]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." Windsurfing Int'l v. AMF, Inc., 782 F.2d 995, 1003 n.12 (Fed Cir.

1996).

Here, Inverness has provided evidence that Acon competes with Inverness and as a result takes market share and lowers prices. While Inverness's claims are unspecific, the damage from such results is generally recognized as substantial. See Polymer Technologies, 103 F.3d at 975-76 (damages may not suffice to compensate a patentee for years of infringement, for "[c]ompetitors change the marketplace").

Acon presents evidence that as most of its domestic revenues stem from sales of allegedly infringing products, an injunction would "virtually shut down Acon's U.S. operations." (Aff. of James McMenamy of 9/15/2003 at ¶ 2.) Acon estimates that, assuming an eighteen month trial schedule, costs stemming from lost sales and reestablishing its products would be substantial. (Aff. of Jixun Lin of 10/16/2003 at ¶ 3.) The most recent affidavits submitted by parties estimate that Inverness possesses 80% of the home pregnancy test market, Acon 10%.

Although Acon will undoubtedly lose profits if the injunction is issued, Inverness has introduced evidence that Acon's sale of infringing products is taking significant business away from Inverness in both the private label level market (for example, the loss of Walmart) and at the branded level. This factor is evenly balanced.

H. Public Interest

"Typically, in a patent infringement case, although there exists a public interest in protecting rights secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by grant of preliminary relief." Hybritech, 849 F.2d at 1458 (affirming a decision not to enjoin the production of infringing hepatitis and cancer test kits).

There is no countervailing public interest served by allowing Acon to use Inverness's patented technology. It is undisputed that consumers have access to different immunoassay devices made by various private manufacturers. Although Acon's private label strips sell at lower prices than certain of Inverness's branded materials, there is no evidence that consumers will not have access to other private label sources.

CONCLUSION

Plaintiffs' motion for summary judgment of infringement of claims 7 and 19 is **ALLOWED** and Plaintiffs' motion for a preliminary injunction (Docket No. 8) is **ALLOWED** with respect to products that violate claims 7 and 19. Defendant's motion for summary judgment is **DENIED** with respect to claims 7 and 19. Plaintiffs shall file a proposed preliminary injunction order consistent with this opinion, and send a disk containing it in .RTF format. Within ten business days, Defendant shall propose an amount of a bond to protect against damages incurred as a

result of the preliminary order until trial, with supporting material.

PATTI B. SARIS
United States District Judge

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